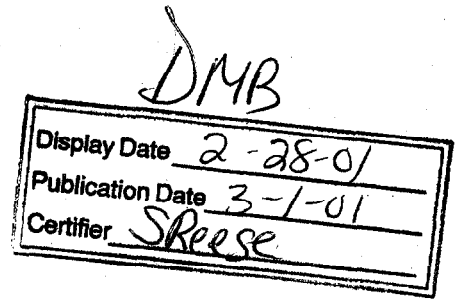
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**




**Food and Drug Administration**

**21 CFR Parts 203 and 205**

**[Docket No. 92N–0297]**

**RIN 0905–AC81**

# Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures; Delay of Effective Date

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; delay of effective date.

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**SUMMARY:** The Food and Drug Administration (FDA) is further delaying, until April 1, 2002, the effective date regarding certain requirements of the final rule published in the **Federal Register** of December 3, 1999 (64 FR 67720). The final rule implements the Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992 (PDA), and the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). FDA is further delaying the effective date for certain requirements in the PDMA final rule relating to wholesale distribution of prescription drugs by distributors that are not authorized distributors of record, and distribution of blood derivatives by entities that meet the definition of a "health care entity" in the final rule. In the **Federal Register** of May 3, 2000 (65 FR 25639), the agency previously delayed until October 1, 2001, the effective date of these requirements. The other provisions of the final rule became effective on December 4, 2000. The agency is taking this action to address concerns about the requirements raised by affected parties.

FDA believes that this further delay of the effective date of certain requirements in the PDMA final rule satisfies the memorandum of January 20, 2001, from the Assistant to the President and Chief of Staff, entitled "Regulatory Review Plan," published in the **Federal Register** on January

24, 2001 (66 FR 7702). That memorandum requested Federal agencies to delay by 60 days the effective date of any regulation that was not effective as of January 20, 2001. The action taken in this document to further delay the effective date of certain requirements of PDMA exceeds 60 days. To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of procedure under 5 U.S.C. 553(b)(A). Alternatively, the agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exceptions in 5 U.S.C. 553(b)(B) and (d)(3). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. As explained in the **SUPPLEMENTARY INFORMATION** section entitled "Need to Further Delay the Effective Date," the delay will give distributors additional time to exhaust inventories of drugs that do not have acceptable pedigrees to avoid economic harm. Additionally, the delay will allow more time for FDA to make recommendations to Congress, for Congress to evaluate those recommendations and, if necessary, time for a regulatory or legislative change.

**DATES:** The effective date for §§ 203.3(u) and 203.50, and the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities, added at 64 FR 67720, December 3, 1999, is delayed until April 1, 2002.

**FOR FURTHER INFORMATION CONTACT:** Lee D. Korb, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

**SUPPLEMENTARY INFORMATION:**

## I. Background

*A. Legislative and Regulatory Requirements for Distribution of Prescription Drugs by Unauthorized Distributors*

PDMA (Public Law 100–293) was enacted on April 22, 1988, and was modified by the PDA (Public Law 102–353, 106 Stat. 941) on August 26, 1992. The PDMA, as modified by the PDA, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331, 333, 353, 381) to, among other things, establish requirements for the wholesale distribution of prescription drugs.

Section 503(e)(1)(A) of the act states that each person who is engaged in the wholesale distribution of a prescription drug who is not the manufacturer or an authorized distributor of record for the drug must, before each wholesale distribution of a drug, provide to the person receiving the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of the drug, including the date of the transaction and the names and addresses of all parties to the transaction.[1] Section 503(e)(4)(A) of the act states that, for the purposes of section 503(e), the term "authorized distributors of record" means those distributors with whom a manufacturer has established an "ongoing relationship" to distribute the manufacturer's products.

On December 3, 1999, the agency published final regulations in part 203 (21 CFR part 203) implementing these and other provisions of PDMA (64 FR 67720). Section 203.50 requires that, before the completion of any wholesale distribution of a prescription drug by a wholesale distributor that is not an authorized distributor of record to another wholesale distributor or retail pharmacy, the seller must provide to the purchaser a statement identifying each prior sale, purchase, or trade of the drug. The identifying statement must include the proprietary and established name of the drug, its dosage, the container size, the number of containers, lot or control numbers of the drug being distributed, the business name and address of all parties to each prior transaction involving

[1] The statement required under section 503(e)(1)(A) of the act is commonly referred to as a drug "pedigree."

the drug, starting with the manufacturer, and the date of each previous transaction. Section 203.3(b) defines "authorized distributor of record" as a distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's products. "Ongoing relationship" is defined in § 203.3(u) to mean an association that exists when a manufacturer and a distributor enter into a written agreement under which the distributor is authorized to distribute the manufacturer's products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer's entire product line, the agreement must identify the specific drug products that the distributor is authorized to distribute.

Thus, the final rule requires unauthorized distributors (i.e., those distributors who do not have a written authorization agreement) to provide a drug origin statement to purchasers showing the entire prior sales history of the drug back to the first sale by the manufacturer. As discussed in the preamble to the final rule (64 FR 67720 at 67747), manufacturers and authorized distributors of record are not required to provide an identifying statement when selling a drug, although the agency encouraged them to do so voluntarily to permit unauthorized distributors to continue to be able to purchase products from them.[2]

*B. Legislative and Regulatory Requirements Restricting Distribution of Blood Derived Prescription Drug Products by Health Care Entities*

Section 503(c)(3)(A) of the act states that no person may sell, purchase, or trade, or offer to sell, purchase, or trade any prescription drug that was purchased by a public or private hospital or other health care entity. Section 503(c)(3)(B) of the act states several exceptions to section 503(c)(3)(A), none of which are relevant to this discussion. Section 503(c)(3) of the act also states

[2]An unauthorized wholesale distributor that purchases a product from a manufacturer or authorized distributor of record without an identifying statement showing the prior sales of the drug could not provide an identifying statement to its purchasers and, therefore, could not conduct further wholesale transactions of the drug in compliance with § 203.50

that "[f]or purposes of this paragraph, the term 'entity' does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law."

Section 203.20 of the final rule provides, with certain exceptions, that no person may sell, purchase, or trade, or offer to sell, purchase, or trade any prescription drug that was purchased by a public or private hospital or other health care entity or donated or supplied at a reduced price to a charitable organization. In § 203.3(q) of the final rule, "Health care entity" is defined as meaning any person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care, but does not include any retail pharmacy or wholesale distributor. Under both the act and the final rule, a person could not simultaneously be a health care entity and a retail pharmacy or wholesale distributor. Thus, under the final rule, blood centers functioning as health care entities could not engage in wholesale distribution of prescription drugs, except for blood and blood components intended for transfusion, which are exempt from the PDMA under § 203.1 of the final rule. Blood and blood components include whole blood, red blood cells, platelets, and cryoprecipitated antihemophilic factor, which are prepared by blood banks who collect blood from donors and separate out the components using physical or mechanical means. Blood derivatives are derived from human blood, plasma, or serum through a chemical fractionation manufacturing process. Examples of blood derivative products include albumin, antihemophilic factor, immune globulin, and alpha-1 anti-tripsin. As discussed in the preamble to the final rule in response to comments (64 FR 67720 at 67725 through 67727), blood derivative products are not blood or blood components intended for transfusion and therefore could not be distributed by health care entities, including full service blood centers that function as health care entities, after the final rule goes into effect.

*C. Events Leading to the Delay of the Effective Date*

After publication of the final rule, the agency received letters and petitions and had other communications with industry, industry trade associations, and members of Congress objecting to the provisions in §§ 203.3(u) and 203.50. On March 29, 2000, the agency met with representatives

from the wholesale drug industry and industry associations to discuss their concerns. In addition, FDA received a petition for stay of action requesting that the relevant provisions of the final rule be stayed until October 1, 2001. The agency also received a petition for reconsideration from the Small Business Administration requesting that FDA reconsider the final rule and suspend its effective date based on the severe economic impact it would have on more than 4,000 small businesses.

In addition to the submissions on wholesale distribution by unauthorized distributors, the agency received several letters on, and held several meetings to discuss, the implications of the final regulations for blood centers that distribute blood derivative products and provide health care as a service to the hospitals and patients they serve. The blood center industry asserts that the regulations, and particularly the definition of "health care entity," will severely inhibit their ability to provide medical care and services to the detriment of client hospitals and the patients they serve, and may disrupt the distribution of blood derivatives to the public. The agency also received a letter from Congress on this issue.

Based on the concerns expressed by industry, industry associations, and Congress about implementing §§ 203.3(u) and 203.50 by the December 4, 2000, effective date, the agency published a document in the **Federal Register** of May 3, 2000 (65 FR 25639), delaying the effective date for those provisions until October 1, 2001. In addition, the May 2000 document delayed the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities until October 1, 2001. The May 2000 document also reopened the administrative record and gave interested persons until July 3, 2000, to submit written comments. As stated in the May 2000 document, the purpose of delaying the effective date for these provisions was to give the agency time to obtain more information about the possible consequences of implementing them and to further evaluate the issues involved.

*D. House Committee on Appropriations Reaction to Agency Delay and Committee's Report Request*

On May 16, 2000, the House Committee on Appropriations (the Committee) stated in its report accompanying the Agriculture, Rural Development, FDA, and Related Agencies Appropriations Bill, 2001 (H. Rept. 106–619) that it supported the "recent FDA action to delay the effective date for implementing certain requirements of the Prescription Drug Marketing Act until October 1, 2001, and reopen the administrative record in order to receive additional comments." In addition, the Committee stated that it "believes the agency should thoroughly review the potential impact of the proposed provisions on the secondary wholesale pharmaceutical industry." The Committee directed the agency to provide a report to the Committee by January 15, 2001, summarizing the comments and issues raised and agency plans to address the concerns.

*E. Public Hearing*

After issuing the delay of the effective date for the relevant requirements of the final rule, the agency decided that it would be in the public interest to hold a public hearing to elicit comment on the requirements from interested persons. In the **Federal Register** of September 19, 2000 (65 FR 56480), the agency announced that a public hearing would be held on October 27, 2000, to discuss the requirements at issue (i.e., the requirements for unauthorized distributors and the provisions relating to distribution of blood derivatives by health care entities). The document set forth the purpose of the hearing and the procedure by which individuals could make a presentation at the hearing. In addition, the document set forth questions the agency wanted hearing participants and comments to address. The hearing was held on October 27, 2000, and comments were accepted until November 20, 2000.

## II. Need to Further Delay the Effective Date

As discussed in section I of this document, the House Committee on Appropriations has directed the agency to provide a report to the Committee by January 15, 2001, summarizing the comments and issues raised and agency plans to address the concerns. The agency is currently

considering the comments and testimony received and preparing its report to Congress. If the agency determines that some type of action is appropriate, this action could take the form of a change or modification to the final rule initiated by the agency or a legislative change initiated by Congress. Obviously, it would take a significant amount of time beyond January 15, 2001, to initiate and carry out either change. The agency believes that a legislative change to the act could take well into the 2001 calendar year.

In its hearing testimony and in a letter submitted on November 3, 2000, the Pharmaceutical Distributors Association[3] noted that if the final rule were to apply to drugs already in distribution as of the effective date of the final rule, a significant number of these drugs would have to be taken out of distribution because of the absence of a proper pedigree. The association specifically stated that if the final rule as published were to go into effect October 1, 2001, distributors would need to stop buying drugs that do not have the required pedigree under the final rule and would have to begin to exhaust existing inventories of drugs that do not have acceptable pedigrees by the beginning of the year 2001 to avoid economic harm. The association specifically sought a decision by the agency that the final rule not apply to prescription drugs already in distribution as of the effective date so those drugs could be distributed.

FDA acknowledges the concerns of the Pharmaceutical Distributors Association and has decided that, in light of the uncertainty regarding how to resolve the issues involved and the possible adverse consequences that could result from implementation of the relevant provisions of the final rule, it is reasonable and appropriate to delay the effective date of §§ 203.3(u) and 203.50 for another 6 months until April 1, 2002. Additionally, the agency has decided to delay the applicability of § 203.3(q) to wholesale distribution of blood derivatives by health care entities until April 1, 2002. This delay will allow time for the agency to make its recommendations to Congress, for Congress to evaluate those recommendations, and, depending on the decisions of

[3]The Pharmaceutical Distributors Association is a trade association representing unauthorized wholesale prescription drug distributors.

the agency and Congress, for a regulatory or legislative change to address the issues raised. Although a further delay of the effective date of the relevant provisions of the final rule is not the exact relief requested by the Pharmaceutical Distributors Association, the agency believes that it accomplishes the same purpose in that it will permit unauthorized distributors to operate for an additional 6 months without concern that the drugs in their inventory may become illegal to distribute and therefore valueless. All other provisions of the PDMA final rule became effective on December 4, 2000. This action should not be construed to indicate that FDA necessarily agrees with or has made decisions about the substantive arguments made in the petitions and other submissions related to implementation of §§ 203.3(u) and 203.50, or § 203.3(q), as it applies to wholesale distribution of blood derivatives by health care entities.

This action is being taken under FDA's authority under 21 CFR 10.35(a). The Commissioner of Food and Drugs finds that this further delay of the effective date is in the public interest.

Dated: February 22, 2001
February 22, 2001.

Ann M. Witt,
Acting Associate Commissioner for Policy.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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